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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,632

11/13/2003

Lawrence M. Kauvar

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EXAMINER

SHAW, AMANDA MARIE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,632	KAUVAR ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17, drawn to method of identifying a desired region of a target nucleic acid using two identification probes which bind to the sequence, classified in class 435, subclass 6.
 - II. Claims 18-27, drawn to a composition comprising a target nucleic acid bracketed by two oligomers which are bound to the sequence, classified in class 536, subclass 24.3.
 - III. Claims 20-33, drawn to a method for assessing the length of a nucleic acid by using one downstream probe and one upstream probe to bracket the segment, and then coupling each repeated sequence in said segment to a signal generating moiety, classified in class 435, subclass 6.
 - IV. Claims 34-37, drawn to a method for detecting SNPs using two probes, one of which binds to a restriction site and subjecting the bound probes to a restriction enzyme that cleaves at the restriction site, classified in class 435, subclass 6.
 - V. Claims 38-44, drawn to a method for detecting SNPs using two probes and a polymerase wherein if the interrogated base is present the assay probe will be incorporated , classified in class 435, subclass 91.2.

- VI. Claims 45-47, drawn to a method for detecting SNPS by hybridizing two labeled probes at the border of said locus and then treating the target with a 5mer assay probe and detecting hybridization, classified in class 536, subclass 23.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product is a nucleic acid with two oligomers hybridized to it. The product as claimed can be made by another and materially different process such synthesized chemically or by isolating a naturally occurring nucleic acid or by one of the methods of III, IV, V, VI.

Inventions I and III, I and IV, I and V, and I and VI are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention do not overlap in scope, the inventions are not obvious variants and the inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention I

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requires the use of two identification probes which are used to bracket a desired region of a target nucleic acid so that it can be observed. The method of Invention III requires the use of two identification probes which are used to bracket a desired region and then coupling each repeated sequence in the region to a signal in order to assess the length of the segment. The method of Invention IV requires the use of two identification probes which bind to the target and then subjecting the target to a restriction enzyme in order to detect a SNP. The method of Invention V requires the use of two identification probes, and assay probe, and a polymerase in order to detect a SNP. The method of Invention VI requires the use of two identification probes, and assay probe which hybridizes to the target in order to detect a SNP.

Inventions II and III, II and IV, II and V, and II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product is a nucleic acid with two oligomers hybridized to it. The product as claimed can be made by another and materially different process such as synthesized chemically or by isolating a naturally occurring nucleic acid or by one of the methods of III, IV, V, VI.

Inventions III and IV, III and V, and III and VI are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the

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inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention do not overlap in scope, the inventions are not obvious variants and the inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention III requires the use of two identification probes which are used to bracket a desired region and then coupling each repeated sequence in the region to a signal in order asses the length of the segment. The method of Invention IV requires the use of two identification probes which bind to the target and then subjecting the target to a restriction enzyme in order to detect a SNP. The method of Invention V requires the use of two identification probes, and assay probe, and a polymerase which in order to detect a SNP. The method of Invention VI requires the use of two identification probes, and assay probe which hybridizes to the target in order to detect a SNP.

Inventions IV and V, and IV and VI are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention do not overlap in scope, the inventions are not obvious variants and the inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention IV requires the use of two identification probes which bind to the target and then subjecting the

target to a restriction enzyme in order to detect a SNP. The method of Invention V requires the use of two identification probes, and assay probe, and a polymerase which in order to detect a SNP. The method of Invention VI requires the use of two identification probes, and assay probe which hybridizes to the target in order to detect a SNP.

Inventions V and VI are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention do not overlap in scope, the inventions are not obvious variants and the inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention V requires the use of two identification probes, and assay probe, and a polymerase which in order to detect a SNP. The method of Invention VI requires the use of two identification probes, and assay probe which hybridizes to the target in order to detect a SNP.

3. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-VI require different searches that are not co-extensive. For instance, a literature for the composition II is not co-extensive with a literature methods of inventions I, III, IV, V, and VI. Additionally, a search for each of the

methods of inventions I, III, IV, V, and VI is not co-extensive with one another. Further, a finding that, for example, that the composition of invention II is anticipated or obvious over the prior art would not necessarily extend to a finding that the method of inventions I, III, IV, V, and VI were also anticipated or obvious over the prior art. Similarly, a finding that one method is novel and unobvious over the prior art would not necessarily extend to a finding that all the methods also novel and unobvious over the prior art.

Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of**

the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634
May 8, 2006


CARLA J. MYERS
PRIMARY EXAMINER